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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,492	02/26/2004	Ramez Emile Nicola Shehada	64693-094	7995

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EXAMINER

TOTH, KAREN E

ART UNIT PAPER NUMBER

3735

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/789,492	Applicant(s) NECOLA SHEHADA ET AL.	
	Examiner Karen E. Toth	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5,15-27,62,68,70,75 and 76 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 62,68 and 70 is/are allowed.
- 6) ☒ Claim(s) 1, 5, 15-27, 76 is/are rejected.
- 7) ☒ Claim(s) 75 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

2. Applicant's request for reconsideration of the requirement for election of Species I-XI of Group B in the reply filed on 11 December 2006 is acknowledged. The traversal is on the ground(s) that searching and examining these species would not place a significant burden upon the Examiner. This is not found persuasive because searching the specifics of 11 embodiments imposes a serious burden upon the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. Claims 1, 15, 18, 21, 23, 27 and 76 are rejected under 35 U.S.C. 102(b) as being anticipated by Miesel (US Patent 6106477).

Regarding Claim 1, Miesel discloses a system comprising an implantable housing (element 10) including a first surface (element 15) and a second surface (element 11) both on the outside of the housing (column 5, lines 43-45); a first sensor for sensing a physiological tissue property proximate to the first surface (column 5, lines 54-55); a second sensor for sensing the same physiological tissue property proximate to the second surface (column 5, lines 3-7); and a processing system in communication

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with both sensors for computing a difference between the results of the physiological tissue property measurements (column 5, lines 5-7; column 7, lines 28-35 and 39-40), where the sensing surfaces may be on substantially opposite sides of the device (Figure 1). The system may be implanted such that the first sensor rests against a first tissue and the second sensor rests against a second tissue.

Regarding Claim 15, the device of Miesel may be used to deliver energy to the tissue proximate to the sensing surfaces, since oxygenation sensing (column 5, lines 19-21) comprises transmission of light.

Regarding Claim 18, Miesel further discloses that the implantable device comprises a power source, electronics, and communications circuits (element 57; Figure 12).

Regarding Claim 21, Miesel further discloses that the device may include an antenna for transmitting signals (column 11, lines 55-57).

Regarding Claim 23, Miesel further discloses that the physiological tissue property being sensed may be temperature (column 5, lines 13-14); and that the system may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40).

Regarding Claim 27, Miesel further discloses that the device may comprise anchors (element 95; column 7, lines 13-17).

Claim Rejections - 35 USC § 103

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4. Claims 5, 16, 17, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Sun (US Patent 6122536).

Regarding claim 5, Miesel discloses all the elements of the disclosed invention, as described above, except for the system being used to sense oxygenation. Miesel further discloses that the sensors disclosed in the preferred embodiment may be supplemented by or replaced by alternate sensors, such as those capable of sensing oximetry or partial pressure of oxygen (column 5, lines 10-13 and 19-22). Sun teaches a similar implantable sensing system that may be used to sense oxygenation (column 1, lines 15-17), since it is well known in the art to use an implantable sensor to monitor tissue oxygenation. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with sensors for sensing oxygenation, as taught by Sun, since it is well known in the art to use implantable sensors to monitor tissue oxygenation.

Regarding claim 16, Miesel discloses all the elements of the disclosed invention, as described above, except for the system comprising a third sensing system configured to sense a physiological property of tissue proximate to the housing that is different from the property sensed by the first two sensors. Sun teaches an implantable sensing system comprising a plurality of sensors, where one sensor may be configured to sense a physiological property of tissue proximate to the system different than a physical property sensed by the other sensors (column 11, lines 14-21), in order to provide a more complete view of a patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the

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system of Miesel with a third sensor configured to sense a different tissue property, as taught by Sun, in order to provide a more complete view of the patient's condition.

Regarding claim 17, Miesel discloses all the elements of the disclosed invention, as described above, except for the sensing systems being located behind optically transparent material. Sun teaches an implantable sensing system with similar sensors that are located behind optically transparent material (elements 46, 48, 50; column 11, lines 14-15 and 17-19), in order to protect the sensors while still allowing accurate sensing to occur. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the sensors behind optically transparent material, as taught by Sun, in order to protect the sensors while still allowing accurate sensing.

Regarding claim 26, Miesel disclose all the elements of the current invention, as described above, except for the sensing systems including optical fibers. Sun teaches an implantable sensing system using optical fibers to connect to a plurality of sensors (column 11, lines 54-56), in order to provide accurate signal transmission. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with optical fibers, as taught by Sun, to provide accurate signal transmission.

5. Claims 20, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Gord (US Patent 5999848).

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Regarding Claim 20, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving power.

Gord further teaches that the device may receive power signals (column 5, lines 34-36) in order to provide power for operation.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the power receiving capability of Gord, in order to provide power for operation.

Regarding Claim 22, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including an antenna for receiving signals.

Gord further teaches that the device may receive signals (column 5, lines 34-36) in order to control or modify operation of the device.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the signal receiving capability of Gord, in order to control or modify operation of the system.

6. Claims 19, 24, 25, 59-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miesel in view of Hines (US Patent 6582365).

Regarding Claim 19, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the processing system being located outside the patient. Hines further teaches that the system includes a signal processing system (column 2, lines 52-54) that is located outside a patient (Figure 1), so that gathered data may be stored and processed for future reference. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to have made the system of Miesel with an external signal processing system, as taught by Hines, so that gathered data may be stored and processed for future reference.

Regarding Claim 24, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show information gathered by the sensing systems. Hines further teaches that the system includes a display that is used to show the gathered physiological data (column 2, lines 52-54), in order to allow medical professionals to examine the results of the gathered physiological data. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the display of Hines, in order to allow medical professionals to examine the results of the gathered physiological data.

Regarding Claim 25, Miesel discloses all the elements of the current invention, as applied to Claim 1, except for the system including a display configured to show data corresponding to the difference between the signals gathered from the two sensing systems. Miesel further discloses that the system may be configured to calculate the difference between the first and second sensors (column 10, lines 31-40). Hines teaches that the system includes a display that is used to show gathered physiological data (column 2, lines 52-54), in order to give an indication of a patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Miesel with the display of Hines used to show data

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corresponding to the difference between the signals gathered by the sensing systems, in order to give an indication of a patient's condition.

Allowable Subject Matter

7. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the methods of claims 62, 68, and 70, including, *inter-alia*, positioning an icon on a display to show the position of a sensing device within a body when receiving information from a device having two sensing systems.

8. Claim 75 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the structure of claim 75, including, *inter-alia*, including a display that is configured to depict an icon representing a device on the display relative to a depiction of the tissue to indicate the position of a device within a body when sensing using an implantable sensor having two sensing systems.

Response to Arguments

9. Applicant's arguments filed 11 December 2006 have been fully considered but they are not persuasive.

Regarding Applicant's argument that Miesel does not disclose a housing configured to be implanted between two tissues where the first and second opposite sensing surfaces rest against the different tissues, the Examiner disagrees. Firstly, the cited passage in the rejection for the second sensor recites "It provides a second pressure sensor on the backside of the arterial pressure sensor this second sensor not being in contact of the vessel which can be used to measure ambient pressure of "gage" pressure." (column 5, lines 3-7) Additionally, the placement of the device is at the discretion of the user; any similar device may be implanted such that one side rests against one tissue and an opposite side rests against a different tissue, as long as it performs the desired function. Applicant's arguments for this art refer to elements NOT CITED by the Examiner. Applicant further argues that the random embodiment chosen to argue the rejection places sensors on the interior of the housing, rather than the exterior as cited in the application; this is not the case, as the sensors are still on an exterior surface – they merely happen to be in the center portion of a "U" shaped device.

10. Applicant's arguments with respect to the rejection using Fitz (US Patent Application Publication 2002/0183629) have been fully considered and are persuasive. The rejection of claims 1, 2, 18-20, 22, 54-56, 65-67, and 69 under Fitz has been withdrawn.

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11. Applicant's arguments with respect to the rejection(s) of claim(s) 1, 5, 16-18, 20, 22, and 24-27 under Sun have been fully considered and are persuasive in the context that Sun does not disclose sensors on opposite sides of a housing for sensing two different tissues. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Miesel in view of Sun (see above).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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